

Application No. 10/824,950
Amendment Dated March 22, 2007
Reply to Office Action of December 22, 2006

REMARKS

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Office Action mailed December 22, 2006, claims 1 and 3-19 have been rejected and claim 3 has been objected to. In response, the Applicants have submitted the following remarks and amended claims 1, 3 and 18. Accordingly, claims 1 and 3-19 are still pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

Claim Objections

Within the Office Action, claim 3 has been objected to because the Examiner indicates that there appears to be a typographical error in the second line of the claim. By the above amendment, the Applicants have amended claim 3 according to the Examiner's suggestion. Accordingly, the Applicants respectfully request that the objection to claim 3 be withdrawn.

Claim Rejections Under 35 U.S.C. §101

Claims 1 and 3-19 have been rejected under 35 U.S.C. §101 because the claimed invention lacks patentable utility. Within the Office Action it is stated that the method claims appear to be an abstract idea rather than a practical application of that idea. By the above amendments, the Applicants have amended claims 1 and 18 according to the Examiner's suggestion thus adding a tangible, useful and concrete method step. Accordingly, the Applicants respectfully submit that the rejection to claims 1 and 3-19 under 35 U.S.C. §101 be withdrawn.

Rejections Under 35 U.S.C. §103

Claims 1, 3 and 6-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,136,690 to Anderson (hereinafter Anderson), in view of the European Heart Journal article by Kardys (hereinafter Kardys). The Applicants respectfully disagree with this rejection.

Anderson relates to vector analysis of ECG arrhythmias. The Anderson reference describes an invention that uses two ECG leads, but does not teach utilizing a three lead system, which renders the possibility of Anderson measuring a 3-D QRST angle impossible. It is stated within the Office Action that while Anderson does not teach defining a relationship between depolarization and repolarization, including measuring a 3-D QRS-T angle, Anderson does indeed teach calculating a variation between stored values of 2D QRST angles

The Kardys reference is a study to assess the prognostic importance of the spatial QRS-T angle for fatal and non-fatal cardiac events. The study investigates whether an abnormal spatial QRS-T angle is a marker of increased cardiovascular disease and mortality in the previous Roderham study, a population-based cohort study in men and woman aged 55 years and over (Kardys, page 1358, column 1). While the Applicants agree that the Kardys reference does indeed teach the existence of 3-D QRS-T angles as it is disclosed in Kardys that the QRS-T angle is to be calculated from a set of orthogonized x, y and z leads of the ECG, the Applicants disagree with the argument made by the Examiner that such teaching makes it obvious to one having ordinary skill of the art at the time of the invention was made to modify the method of Anderson in view of Kardys to utilize a 3-D QRS-T angle calculated from the set of orthogonized x, y and z leads of the ECG since such a modification would allow for assessment of a patient's worsening condition and since such a modification may be easily implemented and is less susceptible to noise. On the contrary the Applicants respectfully argue that there is no indication of any teaching to combine the Kardys reference with the Anderson reference, as while the Kardys reference was published several decades after the Anderson

reference, the Kardys reference does not hint of determining two values representative of a 3-D QRS-T angle and calculating a variation between the first value and the second value. In short, had there been any teaching or suggestion to combine the references, the Kardys reference would have contained some reference, even slight, to utilizing 3-D QRS-T angles, in the manner in which the Anderson reference analyzes 2-D signals.

In contrast to the teachings of Anderson and Kardys, the present invention utilizes a 3-D QRS-T angle, which is more representative of true heart dye pole. The present invention utilizes three lead ECG systems in order to appropriately measure a 3-D QRST angle, which is something that is not obvious in light of Kardys and Anderson.

The Applicants respectfully submit that the age of the cited references indicates a lack of some teaching or suggestion supporting the combination. The Anderson patent was filed on October 31, 1977. The Kardys reference was accepted for publication on March 12, 2003. Even with the benefit of an accepted publication date that is 26 years later than Anderson, Kardys still does not include some teaching or suggestion that the art taught in each reference can and should be combined. In other words, there is no teaching or suggestion in either reference to make the combination made in the Office Action.

Furthermore, the Anderson patent issued on January 30, 1979, and the Kardys reference was published sometime in 2003, after March 12. The present application was filed on April 15, 2004, over a year after the Kardys reference was published. The Applicants respectfully submit that if the combination of the cited references was obvious, as is stated in the Office Action, then it is probable that such a combination would have been made prior to the filing of the present application. Therefore, the Applicants submit that this combination of references is indeed not obvious.

The amended independent claim 1 is directed to a method of using an electrocardiogram signal comprising assessing a patient's cardiac vulnerability to sudden cardiac death by determining a first value representative of a 3-D QRST angle relationship for a first beat of the electrocardiogram signal, determining a second value representative of the 3-D QRST angle for the second beat of the electrocardiogram signal, wherein determining the first and second values defines a relationship between

depolarization and repolarization, calculating a variation between the first value and the second value, and outputting said calculated variation to an output device. As discussed above, neither Anderson nor Kardys teach or make obvious the steps of calculating a variation between a first and second value representative of a 3-D QRST angle. For at least these reasons, the independent claim 1 is allowable over the teachings of Anderson, Kardys and their combination.

Claims 3 and 6-7 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson, Kardys and their combination. Accordingly, claims 3 and 6-7 are also allowable as being dependent upon an allowable base claim.

Claims 4-5 and 8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of U.S. Patent Application No. 2004/0220635 to Burnes (hereinafter Burnes). Claims 4-5 and 8 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claims 4-5 and 8 are also allowable as being dependent upon an allowable base claim.

Claims 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of U.S. Patent No. 4,732,157 to Kaplan et al. (hereinafter Kaplan). Claim 9 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claim 9 is also allowable as being dependent upon an allowable base claim.

Claims 10 and 11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of U.S. Patent No. 5,265,617 to Verrier et al. (hereinafter Verrier). Claims 10-11 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claims 10-11 are also allowable as being dependent upon an allowable base claim.

Claims 12 and 14-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Ralph et al. (hereinafter Ralph). Claims 12 and 14-16 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claims 12 and 14-16 are also allowable as being dependent upon an allowable base claim.

Claim 13 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys, and further in view of Ralph and Verrier. Claim 13 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claim 13 is also allowable as being dependent upon an allowable base claim.

Claim 17 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys, and further in view of Ralph and Burnes. Claim 17 is dependent upon the independent claim 1. As discussed above, independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claim 17 is also allowable as being dependent upon allowable base claim.

Claim 18 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys and Kaplan. Kaplan merely relates to an apparatus and method for quantifying variability and physiological wave forms, but like Anderson and Kardys, does not teach or make obvious defining a relationship between depolarization and repolarization, including measuring a 3-D QRS-T angle. Therefore, for the same reasons as discussed above with respect to claim 1, the Applicants respectfully submit that claim 18 is also allowable over the teachings of Anderson, Kardys, Kaplan and their combination.

Claim 19 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys, and further in view of Kaplan and Verrier. Claim 19 is dependent upon independent claim 18. As discussed above, the independent claim 18 is allowable over the teachings of Anderson, Kardys, and Kaplan. Accordingly, Claim 19 is also allowable as being dependent upon an allowable base claim.

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For these reason, Applicants respectfully submit that all claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (414) 271-7590 to discuss the same that any outstanding issues may be expeditiously resolved.

Respectfully submitted,

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